Anthem
And Its Affiliated HMO

National Pharmacy and Therapeutics Committee

The purpose of the National Pharmacy and Therapeutics (P&T) Committee is to review various federal legend drugs and insulin products as well as related supplies covered under the pharmacy benefit. The functions of the P&T Committee are as follows:

- Research and evaluate the selection and therapeutic use of pharmaceuticals;
- Recommend formulary status and what position or tier covered prescription medications should occupy on formulary;
- Identify trends, clinically significant factors and nationally recognized standards regarding accepted utilization of prescription medications; and
- Review and recommend programs and other initiatives that are designed to help promote nationally recognized, effective and proven utilization of pharmaceutical benefits. This includes, but is not limited to, drug utilization evaluation programs, drug utilization review programs, prior authorization criteria development, quantity supplies, cross-brand initiatives, drug profiling initiatives and drug compliance programs.

The P&T Committee meets to review the formulary four times each year.

The P&T Committee makes clinically based recommendations that help promote access to quality medications and, when appropriate, cost-effective utilization of benefits. Accordingly, the P&T Committee review process consists of two interdependent committees:

- Clinical Review Committee (CRC)
- Value Assessment Committee (VAC)

Collectively, these two committees constitute the P&T Committee.

Clinical Review Committee (CRC)

CRC Purpose and Decision Making Guidelines

The purpose of the CRC is to clinically review products, as discussed above, to determine whether the specific product is efficacious and safe. The CRC is responsible for reviewing the clinical aspects of various drugs in a therapeutic class or used to treat a particular condition. The CRC follows the necessary policies and procedures to consistently document how the clinical designation was established for efficacy and safety of a drug product. Effectiveness data, when available and clinical attributes are also considered by the CRC. The CRC review may also include, but is not limited to, the following:

- Food and Drug Administration (FDA) approved uses;
- FDA approved package inserts;
- Critically and/or scientifically validated findings;
- Information in major or peer reviewed medical publications;
- Recommendations of recognized experts or specialists; and/or
- Practice pattern and utilization data.

CRC Assignment of Clinical Designation

The CRC conducts its clinical review and makes recommendations for formulary consideration to the Value Assessment Committee (VAC). Clinical designations will only be assigned for branded products that do not have a generic available. The applicable designations that the CRC may assign are as follows:

- Favorable
- Comparable
- Insufficient Evidence
- Unfavorable

The **favorable designation** means that based upon the data available at the time of the review, the drug provides a better overall treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options. In cases where no other pharmacotherapeutic option exists, this designation may include drugs that have sufficient evidence that they are better than usual care or placebo.

The **comparable designation** means that based upon the data available at the time of the review, the drug provides a comparable treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options.

The **insufficient evidence** designation means that based upon the data available at the time of the review, the drug provides an unclear treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options.

The **unfavorable designation** means that based upon the data available at the time of the review, the drug provides an unfavorable treatment profile for the majority of individuals taking the product as compared to other available products within the therapeutic class of drugs or other available treatment options.

CRC Clinical Comments

The CRC may also, as part of its clinical review, make substantive clinical comments about the products under review or issues pertaining to the therapy of a disease the drug(s) is/are used to treat. These comments are intended to provide the VAC with additional considerations beyond the clinical designations. Clinical comments may be used by the CRC to highlight important safety, efficacy, or clinical attribute concerns. For example, clinical comments may be used to provide further detail supporting a clinical designation, to further differentiate important clinical points between products given the same clinical designation, or to emphasize key clinical concerns in the treatment of a disease state pertaining to the choice of drug therapy.

Advisory Panels

The CRC has the authority to establish or solicit input from expert advisory panels regarding the clinical designations, clinical comments and edit criteria. These expert advisory panels include clinicians who are recognized in that clinical area and who are considered experts in that field of practice. Information and opinions from the advisory panel reviews are presented to the CRC and used by the CRC in their decision-making process. Qualified members of the CRC may participate on advisory panels. Expert advisory panels are in place to address the following clinical areas, including but not limited to:

- Behavioral Health
- Neurology
- Cardiology
- Endocrinology
- Gerontology

CRC Membership

The CRC consists of practicing physicians and pharmacists representing our health plan. The following areas of medical expertise are currently represented:

- Allergy/Immunology
- Cardiology
- Endocrinology
- Family Practice
- Gastroenterology

- Geriatrics
- Infectious Disease
- Internal Medicine
- Neurology
- Obstetrics and Gynecology
- Oncology
- Pediatrics
- Psychiatry
- Rheumatology

Value Assessment Committee (VAC)

VAC Purpose & Decision Making Guidelines

The purpose of the VAC is to make recommendations regarding the formulary/tier assignment and clinical edits applied to covered prescription medication based on the CRC decisions.

The VAC review and tiering process must take into account the clinical designations made by the CRC. This means that the VAC cannot tier (or place edits on) a drug with a lesser clinical designation lower than another drug with a greater clinical designation; however, insufficient evidence and unfavorable designations are considered equivalent when making tiering decisions. In addition to the clinical designations, the VAC will take into account the member impact associated with drug tiering decisions and implementation of edits.